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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,655	05/01/2006	Kazuhiro Machida	0425-1257PUS1	3246

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EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1633

NOTIFICATION DATE	DELIVERY MODE
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01/08/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/577,655	Applicant(s) MACHIDA ET AL.	
	Examiner Janet L. Epps-Smith	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 6-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :5/01/06; 8/21/06; 8/20/08; 11/20/08.

DETAILED ACTION

Election/Restrictions

1. In the reply filed 7-07-2008 Applicants elected invention Group I, claims 1-2 and 4-5, drawn to DNA encoding a protein having 16-position hydroxylating enzymatic activity, partly or entirely or its variant. In addition, in the reply filed 10-22-08 Applicants elected variant A-1, drawn to a continuous nucleotide sequence from base 1322 to base 2548 of SEQ ID NO: 1.
2. Claims 3, and 6-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/07/2008.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-2 and 4-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (Written Description).
5. Claim 1 is broadly drawn to a genus of "DNA" participating in the biological transformation of a macrolide compounds (11107B) into a 16-position hydroxy macrolide compound represented by formula II (11107D), wherein the genus of DNA

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includes a DNA comprising a DNA encoding a protein having 16-positoin hydroxylating enzymatic activity, or ferredoxin, partly or entirely or its variant. Claims 2, and 4-5 depend from claim 1, and are therefore rejected for the reasons set forth below.

6. Applicants have provided the structures of the following DNA molecules according to the present invention:

1. A continuous nucleotide sequence from base 1322 to base 2548 of SEQ ID NO: 1;
2. A continuous nucleotide sequence from the base 420 to 1604 of SEQ ID NO: 2;
3. A continuous nucleotide sequence from the base 172 to base 1383 of SEQ ID NO: 3;

7. However, Applicants have not provided a clear description of the full scope of variant sequences of the above sequences, wherein said variants are capable of hybridizing to these sequences, under undefined hybridization conditions, and further have the ability to participate in the biological transformation of a macrolide compounds (11107B) into a 16-position hydroxy macrolide compound represented by formula II (11107D).

8. Additionally, Applicants have not provided a clear description of how the above sequences are structurally related such that the ordinary skilled artisan would be able to make a clear correlation between the DNA nucleotide sequences of the disclosed species, and the corresponding functional activity recited in the instant claims, such that the structures of variant sequences of the above sequences could be predicted.

9. There is no clear guidance provided in the specification as filed, which would allow the skilled artisan to predict the structures of the full scope of DNA molecules encompassed by the instant claims.

10. See the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, "Written Description" Requirement. These guidelines state: "[T]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention."

11. See MPEP § 2163, which states "[A] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence."

12. In the instant case it is concluded that there is not a sufficient amount of relevant identifying characteristics to describe the full scope of DNA molecules encompassed by the instant claims. Applicants have only provided guidance for the description of DNA

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molecules of SEQ ID NOs: 1-3, which possess the recited function of 11107B which encodes a protein having enzymatic activity in hydroxylating the 16-position of the macrolide compound. There is no guidance provided for varying the structures of these sequences in order to produce variants of these DNA molecules having the same functional characteristics of the DNA molecules of SEQ ID NO: 1-3.

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-2 and 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakajima et al. (WO03/040370 A1; Japanese; citations given from English equivalent document US 2005/0084859 A1).

15. Nakajima et al. disclose a plasmid DNA sequence comprising the sequence of SEQ ID NO: 237, see example 53, paragraph [1365]-[1366]. The plasmid DNA was transformed into E. coli. SEQ ID NO: 237 of Nakajima et al. is over 80% identical to nucleotides 1322 to 2548 of SEQ ID NO: 1 of the instant application. Therefore, since the scope of the instant claims encompasses DNA sequences which encode partly or entirely a DNA molecule comprising nucleotides 1322 to 2548 of SEQ ID NO: 1, the DNA sequence of SEQ ID NO: 237 of Nakajima et al. is interpreted as reading on the claimed invention.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633